

#### REMARKS

Claims 6 to 20 are in the application. Claims 1 to 5 have been cancelled. Claims 14 to 20 have been added. Claims 6 to 13 have been amended. Support for the newly added claims and amendments lie in the claims as originally filed or in the specification. No new matter is believed added. Applicants reserve their right to file divisional or continuation applications on all cancelled or deleted subject matter.

#### **Restriction under 35 USC §121**

Claims 1 to 13 have been made the subject of a restriction under 35 USC §121 into 2 groups:

- Group I: Claims 1 to 5 are drawn to compounds and compositions of Formula (I).  
Group II Claims 6 to 13 are drawn to methods of inhibiting the binding of acetylcholine to its receptors, etc.

Applicants confirm their election, without traverse, for the methods of use of the compounds of Formula (I) as contained in Group II. The claims in Group II have been amended to recite the compounds and compositions of Group I. The claims of Group I have been cancelled accordingly.

#### **Rejection under 35 USC § 112**

Claims 5 to 13 are rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

It is believed that the Examiner intended the rejection to be over claims 6 to 13 as claim 5 was contained in the restriction to Group I. Clarification is requested.

The Examiner cites a number of factors to indicate that the specification is deficient in its ability to essentially teach how to make and how to use the compounds of the present invention in the activities as claimed herein.

The Examiner has failed to properly read Claim 6. Claim 6 is merely recites a requirement that the composition (of Claim 1) inhibit the binding of acetylcholine to an acetylcholine receptor in a mammal. This method is not tied to the treatment of a particular disease state or respiratory condition. In fact, the specification provides more than ample support for such a claim. See the second binding assay, page 6, lines 23 to

30 that provides for a pan-muscarinic antagonism screening assay against the M1 to M5 acetylcholine receptors. This is in fact a means to determine agonism or antagonism of each of the muscarinic receptors. The skilled artisan would readily understand the significance of this assay and the potential limitations of compounds tested therein. This is a well known art recognized assay. The method of claim 6 does not require "treatment of a disease state". The claim limitations in Claim 6 are such that a compound of Formula (I) contact a particular receptor and that this contact is made by a route of administration, e.g. inhalation for receptors in the respiratory tract.

The first and the third described assay, appearing on page 5, lines 29 to 32, page 6, lines 1 to 21; and pages 7, lines 1 to 32, and page 8 lines 1 to 32, are also art recognized variations on accepted *in vitro* assays. Lastly, the fourth assay contained in the specification is directed to *in vivo* inhibition. The "Methacholine-induced bronchoconstriction—potency and duration of action" assay on page 9, lines 1 to 24 will demonstrate inhibition of the muscarinic acetylcholine receptors *in vivo*. Again, this is an art recognized assay.

Applicants do not need to provide test data to show sufficiency of the specification. The art is now suitably predictable in this field that use of *in vitro* antagonism data will establish utility of the invention.

The compounds of the present invention are already art recognized anti-cholinergic agents (see column 1, lines 20-26 of Zirkle, US 2,800,481). Therefore, the skilled artisan already has in their possession the knowledge that compounds of Formula (I) are useful as anti-cholinergics. Zirkle did not teach nor suggest the use of the compounds described therein for the treatment of disease states which require anticholinergic activity by the inhaled route of administration, suitably by the mouth, with a dry powder inhalation composition. The instant specification provides the skilled artisan four (4) assays directly related to supporting the method claims herein.

The specification provides for formulation details, amounts, how to use/administer such (dry powder formulations) of compounds of Formula (I), and reference additional patents on the various devices for such formulations.

In view of these remarks, reconsideration and withdrawal of the rejection to the claims is respectfully requested.

### **Rejection under 35 USC §112**

Claims 6 - 13 rejected under 35 US C§112 as being indefinite. Applicants respectfully traverse these rejections.

Claims 6 and 7 depend from non-elected claim 1. Claims 6 and 7 have been amended to incorporate the compounds of Formula (I).

Claims 8 to 13 are rejected due to their dependency on Claim 7. As Claim 7 has now been amended to be independent it is believed that this rejection is rendered moot.

In view of these remarks and amendments, reconsideration and withdrawal of the rejection to the claims is respectfully requested.

### **CONCLUSION**

It is believed that the claims, as amended, are now all in condition for allowance. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case, the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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